Additive/Subtractive Computer Aided Manufacturing of Customized Implants Based on Virtual Prototypes

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Abstract. Using of personal implants for reconstruction of craniofacial harms become more and more important due to the better performance, good fit in the implant area, reduced surgical time and better cosmetic results then traditional mesh. Although creating of such implants is a complex task, but in this article structured process workflow with clearly defined steps was introduced. All of the steps were evaluated with solving of clinical case. In this second article using innovative manufacturing methods based on 3D Reconstruction/Modelling and final result were explored in details.

Keywords: Virtual engineering · 3D modelling · Craniofacial surgery · Patient specific implants · CAD CAM surgery · Reconstructive surgical procedure

1 Introduction

In any craniofacial reconstruction whether secondary to trauma, ablative tumour resection, infection and congenital/developmental deformities, restoration of aesthetics and function is the primary goal and calls for precise pre-surgical planning and execution of the plan [1–7].

Development of computer aided design (CAD) and computer aided manufacturing (CAM) systems that adapt to the surgeons' needs has resulted in a gamut of the armamentarium for computer-assisted surgery. Advances in manufacturing technology and material science have led to the possibility of turning such virtual model or design

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into reality as physical replica models, surgical guides or cutting jigs or splints for intraoperative use and patient-specific implants.

The success and longevity of implants depend upon factors like material characteristics, the design of the implant and the surgeon's experience. This new level of automation gave the opportunity to fabricate custom designed implants which fulfil all of previously defined requirements for reconstruction of craniofacial defects. Custom implants for the reconstruction of craniofacial defects have gained importance due to their better performance over their generic, standardized meshes and plaques. This is attributed to, the precise adaptation to the region of implantation, that reduces surgical times, in turn leading to lesser chances for infection, faster recovery and better cosmetic results [8–10].

CAD/CAM systems have enabled the ability to design and manufacture custom implants at an acceptable cost in a reasonable time. Additive manufacturing technologies as stereolithography (SLA), polyjet, fused deposition modelling; 3D printing, selective laser melting (SLM), selective laser sintering (SLS), electron beam melting (EBM) and direct metal deposition (DMD) made possible for manufacturing of anatomic parts with high level of complexity without any significant design and technology constraints. These technologies also opened completely new field of designs with best strength to weight ratio and that are lattice structures. Best advantage for SLS, SLM and EBM methods is the direct production with well-known biocompatible materials like titanium alloy Ti6Al4V and CoCr. Growing importance of polymers as materials for implants like polyetheretherketone (PEEK) is possible due to FDM facilities.

2 Process Flow

The complete process workflow for generating custom implants is shown in Fig. 1 and the design steps were described in previous article "Creation of custom implants using 3D modelling based on CT-scan data and virtual prototypes (part 1)".

The result from the 3D modelling process is the final shape of the implant, shown on Fig. 2. It follows head's natural shape and has very good eye orbit restoration with enough thickness to fulfil production constraints.

Aim of this article is to present production steps from process workflow to derive individual design variants and to create patient-specific custom skull implants for the facial bones, frontal and temporal regions by using innovative reverse engineering and manufacturing methods based on CT-data.

The implant could be produced by adding material layer by layer additive manufacturing, commonly known as "3D printing", or by machining – subtractive manufacturing [11].

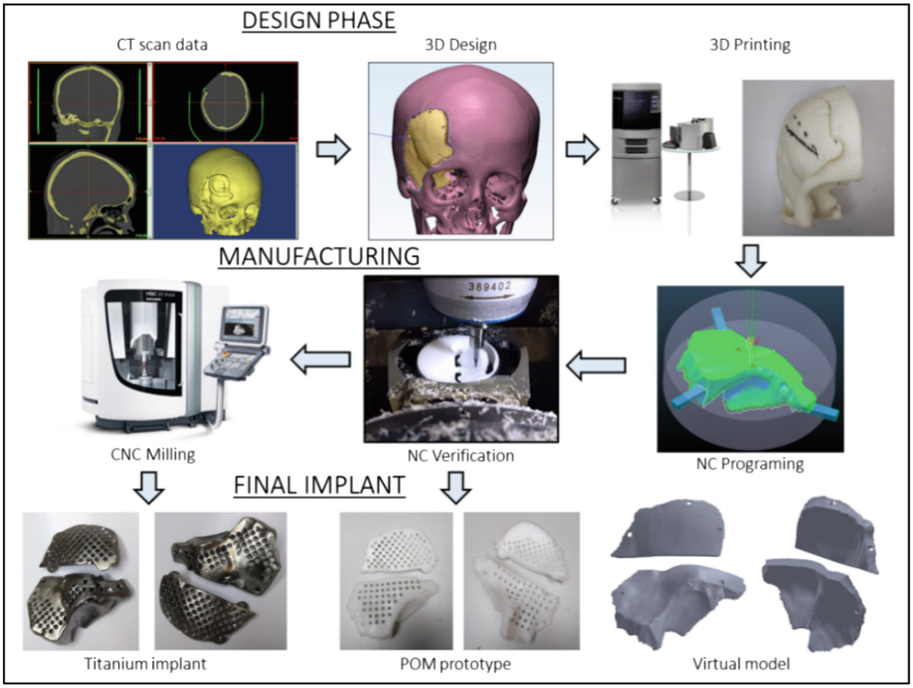

Fig. 1. Process flow for design and manufacture of CAD/CAM generated implants.

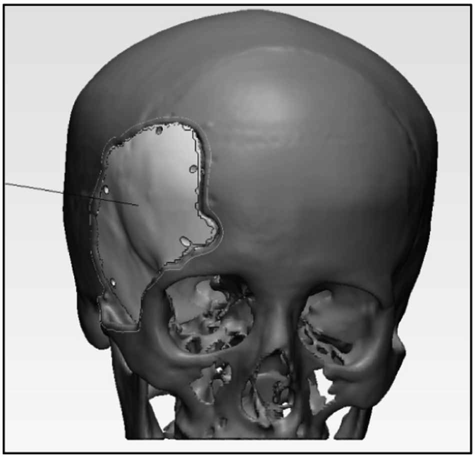

Fig. 2. The final shape of the implant in 3-matic.

3 Manufacturing – Additive

Fastest way to have a real version of the implant from computer 3D model with who is possible to sit down and discuss it with the surgeons responsible for the operation is by using additive manufacturing technology. This step is crucial as it serves as an accurate assessment for the overall quality of the shape and the fitting of the implant. In this step, it is possible to find oversights that on 3D weren't noticeable. Additionally, creating a prototype will allow the design team to not only evaluate the implant, but also inspect for possible issues with the upcoming manufacturing.

The FDM Dimension Elite 3D printer by Stratasys available at the "CAD/CAM/CAE in industry" laboratory located in the Faculty of industrial technology at the Technical university of Sofia - Bulgaria and it is used for the creating of the first phase prototype shown on Fig. 3.

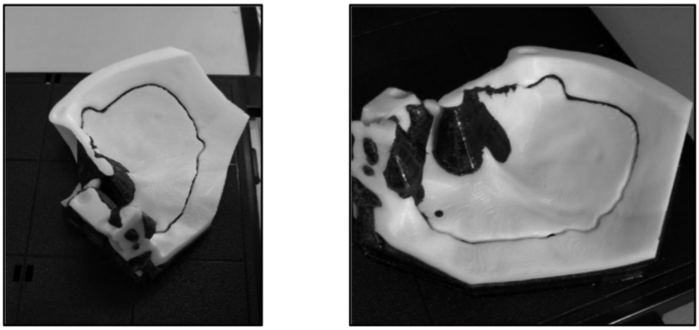

Fig. 3. The 3D printed implant inside the printer.

After cleaning the support material, the implant takes the shape shown on Fig. 4.

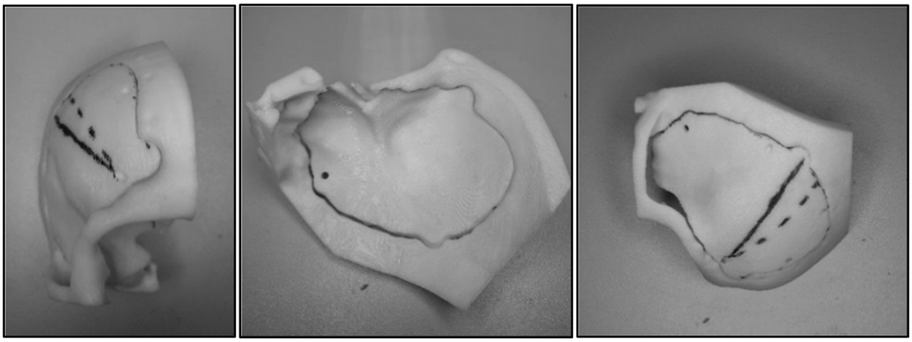

Fig. 4. The 3D printed implant with part of the skull.

Main advantage of the 3D printed design is that it allows final development stages to be planned with surgeons as attachment, holes and cut-outs.

Additive technology as SLM with certificated biocompatible titanium alloy TiAl6V4 could be used for direct production of the implant, but especially for this case balance was not on this side, because as shown on Fig. 3 support structures are commensurable with the volume of the implant. That increases the material consumption, build time, post-processing time and finally cost price. It's important to put into account possible process failures that cause loss of material and most valuable time.

4 Manufacturing – Subtractive

For manufacturing of the implant several steps have been taken:

- Choosing the equipment and workpiece
- Preparing the model for manufacturing
- Creating the NC program using Powermill
- Virtual verification of the tool paths using Vericut
- Physical verification of the tool paths using POM workpieces
- Manufacturing the implant from titanium
- Post-processing and finishing.

4.1 CNC Milling

The DMG Ultrasonic 20 (Fig. 5) milling centre is used for the manufacturing of the prototype, it is available at the "CAD/CAM/CAE in industry" laboratory located in the Faculty of industrial technology at the Technical university of Sofia – Bulgaria.

With the Ultrasonic technology developed in collaboration with SAUER, DMG MORI has for many years now been offering high-performance machine tools for the high-precision 5-axis machining of complex workpieces made of advanced materials. The tool holders with adapted actuator technology are changed into the milling spindle simply and automatically. Each of these holders contains so-called piezo elements, which are activated by a program-controlled inductive system with a high frequency of between 20 and 50 kHz. The actual tool rotation is thus superimposed with an additional tool movement in the longitudinal direction so that a defined amplitude, which can be programmed in the NC-program, in the range of up to more than 10 μm is generated on the cutting edge of the tool or on the grinding layer. During grinding, drilling and milling this Ultrasonic superimposition of vibrations has a direct, positive impact on process forces, metal removal performance and tool service life and thus on the machining result in the form of cost efficiency and a accuracy.

The Ultrasonic results in a higher removal rate, accurate edge machining and up to 40% reduced process forces in the machining of advanced materials such as glass, ceramics, titanium, composite materials and hard metal. Deflections are minimized while workpiece accuracy and process reliability are increased [12].

Fig. 5. DMG MORI Sauer Ultrasonic 20 milling center.

Milling Titanium
Titanium milling is a highly time-intensive process. A major portion of the costs of titanium products are associated with the complexity and time spent machining them, rather than the scarcity of the metal. The arc of engagement of the cutter has a direct impact on its cutting speed. If the arc of engagement of the cutter is larger, it will take more time to cut.

Since machining titanium components represents roughly 40% to 50% of cost, companies continuously concentrate on finding new approaches to improve speed and lower cost. Nevertheless, extreme care is essential to maintain the quality of the product and ensure the tools remain in good condition. Since titanium is a heat-resistant material, the heat generated during the cutting process is not dissipated in the metal, as it would be in aluminium or steel. Instead, the cutting tool absorbs the heat. Excessively aggressive milling could cause combustion due to the low thermal conductivity of titanium. Moreover, although the hardness of titanium may not be as good as other materials, titanium is abrasive in nature, thus causing further tool damage. The edge of the tool is required to be protected by dissipating the heat generated during the milling process through the use of coolants.

Tools are subjected to wear and tear when used in any type of metal machining. However, extra precautions need to be taken in the case of titanium to have a longer tool life without compromising a sustainable and profitable cutting speed. Special tools designed for titanium machining are necessary, even the higher price range, in the case of manufacturing only a single part, in the case of an implant, it is recommended.

Titanium 6AL4V and 6AL4V ELI, alloys made of 6% Aluminium and 4% Vanadium, are the most common types of titanium used in medicine. Because of its harmonizing factor with the human body, these titanium alloys are popularly used in medical procedures, as well as in body piercings. Also known as Gr. 5 and Gr. 23, these are some of the most familiar and readily available. The workpiece is in the shape of a disk (Fig. 6).

Composition (Mass-%):		**Properties**		
Ti	89,8	Type		5
Al	6	Vicker's hardness	HV 10	353
V	4	Coefficient of thermal expansion	25 - 500°C	9,8 x 10-6K-1
Fe	< 1	Density		4,43 g/cm3
		0,2% Elongation limit	Rp 0,2	828 MPa (N/mm2)
		Tensile strenght	Rm	895 MPa (N/mm2)
		Ductile yield	A5	10%

Fig. 6. Interdent medical titanium material specification.

Milling titanium requires specialized tools as well. Due to the low thermal conductivity of the titanium, the heat dissipates in the cutting tool instead of the workpiece. This leads to the requirement for specialized equipment. A set of milling tools specifically designed for titanium machining are prepared. With the workpiece and machining tools selected, the next stage of preparing the model for manufacturing can begin.

4.2 Virtual Model

Due to the limitations of the titanium disk, the implant is separated into two pieces that are tied together with medical titanium thread and then connected to the skull. A set of holes are also added which serve as the connection points between the implant and the skull. The first step of editing the 3D geometry of the implant is to separate the 2 pieces using a flat surface within the Materialise Magics software as shown on Fig. 7.

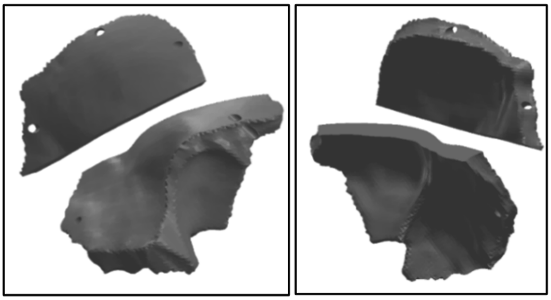

Fig. 7. Separating the 2 pieces using a flat surface.

A set of bulges and indentations are added (Fig. 8) that are positioned on the same flat surface that was used for the separation. Their purpose is to not only connect the two parts of the implant, but also to ensure a better fit and prevent any unwanted movement of the pieces.

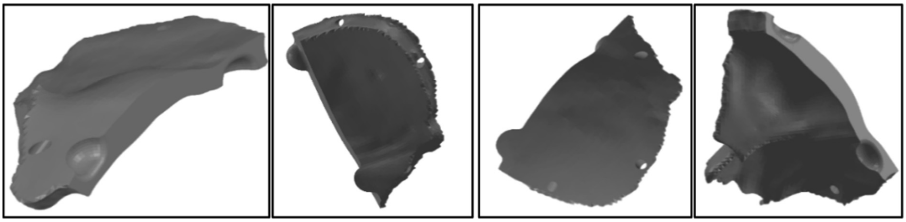

Fig. 8. Creating a set of bulges and indentations.

A set of support square rods is also added to the model. They serve as holders that keep the implant connected to the workpiece after the machining is finished as shown on Fig. 9. They will be partially milled allowing the implant to be manually removed from the workpiece after the machining is finished. With this step completed, the next stage of creating the NC program can begin.

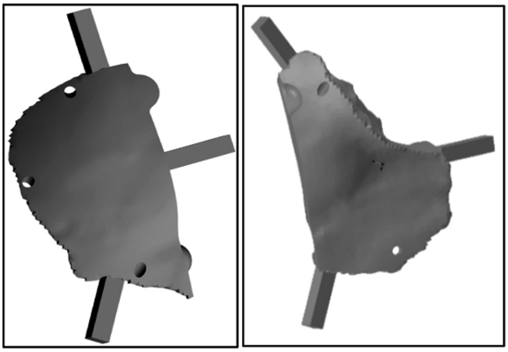

Fig. 9. Creating a set of bridges.

4.3 NC Programing

PowerMill CAM software provides many strategies for optimizing tool paths and reduce tool load in high-speed and 5-axis milling machines.

The NC program begins with a roughing operation on both sides (Fig. 10) of the implant with a 3 + 2 axis strategy. This operation removes most of the material but leaves a rough surface finish on the implant.

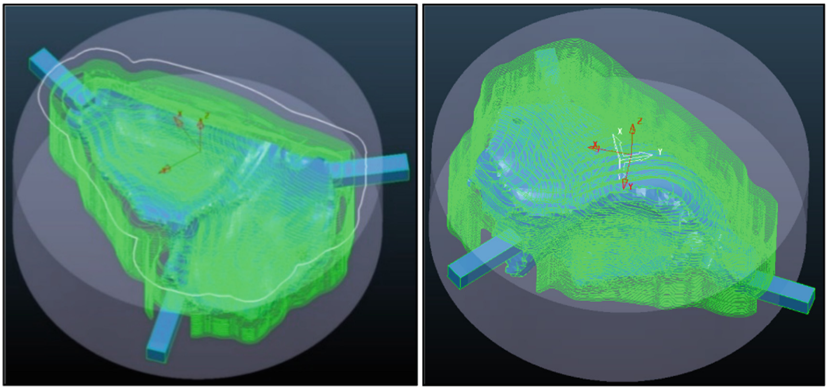

Fig. 10. Rough milling of the implants.

The value for step over, or the vertical distance travelled between each transition, defines the quality of the surface. In the next operation of fine milling the value is lower in order to achieve a better surface finish but machining time increases. Powermill visualizes the contours and they can be seen on Fig. 11.

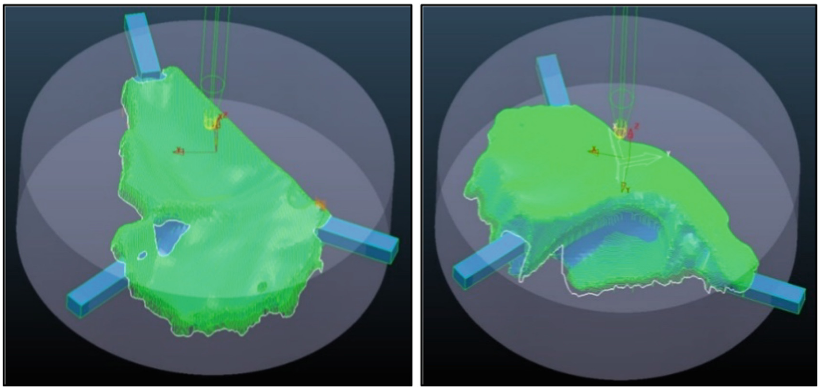

Fig. 11. Fine milling of the implants.

The process of rough and fine machining is repeated for both pieces of the implant. Because of the complex geometrical shape, that is common in cranioplasty implants, some areas of the implants require a more advanced approach to manufacturing and the use of 5 axis milling. It involves simultaneous coordinated movement of all 5 axis of the machine. The milling process is shown on Fig. 12.

With the NC program completed for both pieces the next stage of verification can begin. It is separated into Virtual verification using NC simulation software and subsequent physical verification using a POM workpiece.

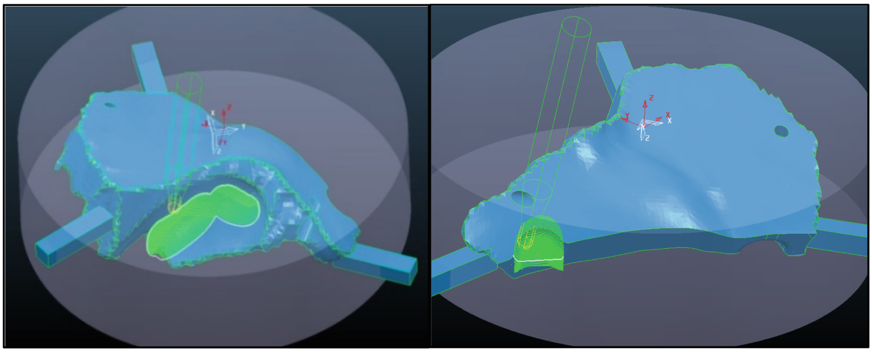

Fig. 12. Areas of the implant using 5-axis machining.

5 NC Verification

5.1 Virtual NC Verification

After the NC programs are finished a verification of the machine movements is necessary. In this case it is done using the software Vericut.

The Vericut software, has become the industry standard for simulating CNC machining in order to detect errors, potential collisions, or areas of inefficiency [14].

One of the features of the Vericut software is that it allows the use of a pre-made work environment for the machine. In this case the DMG Ultrasonic 20 layout is loaded (Fig. 13a). Afterwards the workpiece is positioned in the holder with the correct coordinate system and the milling simulation can begin (Fig. 13b).

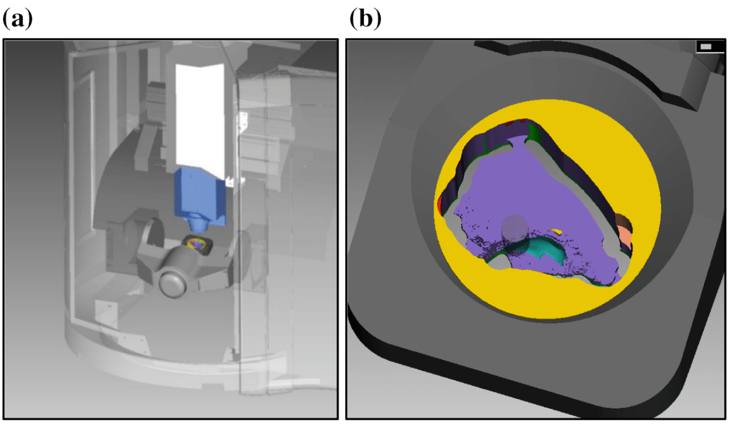

Fig. 13. (a) DMG Ultrasonic 20 layout, (b) The milling simulation process.

After multiple validation checks the simulation goes through. The program verifies the tool paths and the next stage of physically testing the NC program can begin.

5.2 NC Physical Verification

A second verification of the NC programs completed and verified with Vericut was performed using plastic workpiece to evaluate manufacturing quality and accuracy. A POM workpiece is prepared with the same dimensions as the titanium disks only difference was feed and speeds. Achieved result is shown on Fig. 14.

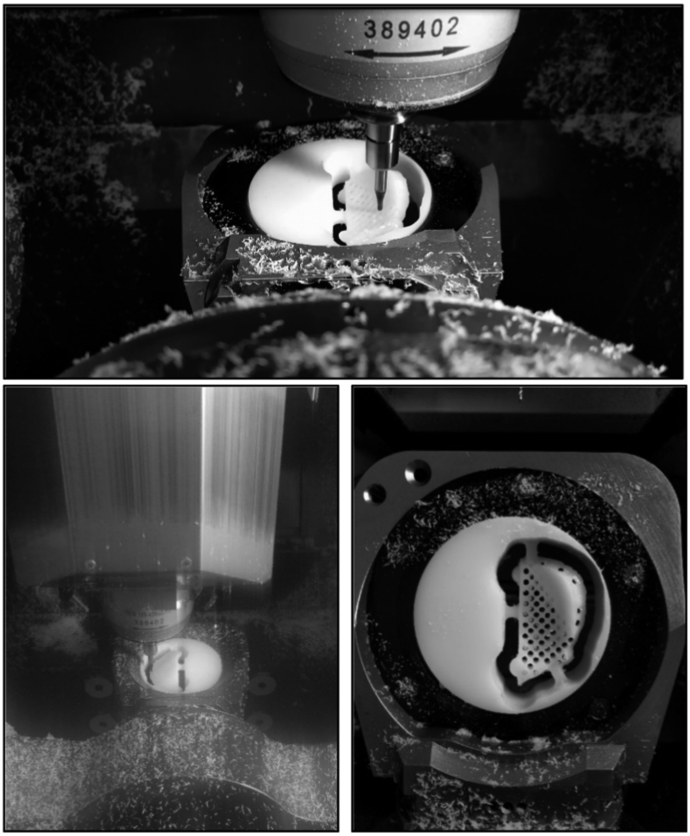

Fig. 14. Milling of a POM workpiece.

With the second verification test completed the results are inspected. The two implant pieces, shown on Fig. 15, verify the NC program, the desired surface quality and overall shape.

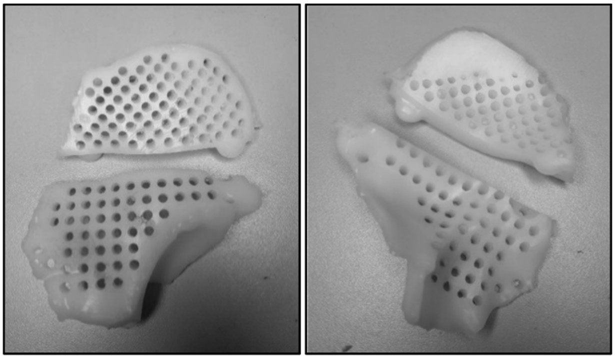

Fig. 15. The machined POM implants.

After two verification, one virtual and one physical, the machining of the titanium alloy could begin. The machining of each piece takes approximately 6 h and the resulting pieces can be seen in the next paragraph.

5.3 Post-processing of the Implant

Each step in the process workflow for producing medical devices presents particular challenges. At the final step surface finishing that removes any sharp edges or corners which could damage the patient or surgeon during and after the surgery should be done. Because of the complex geometrical shapes of the implant the process is quite delicate and time consuming, but of equal importance since any leftover sharp deformations could have an impact on the overall success of the implanting operation.

The finishing procedure is done manually by hand and the final shape of the implant can be seen on the Fig. 16. The 2 implant pieces weight a total of 85 g (respectively 30 and 55 g).

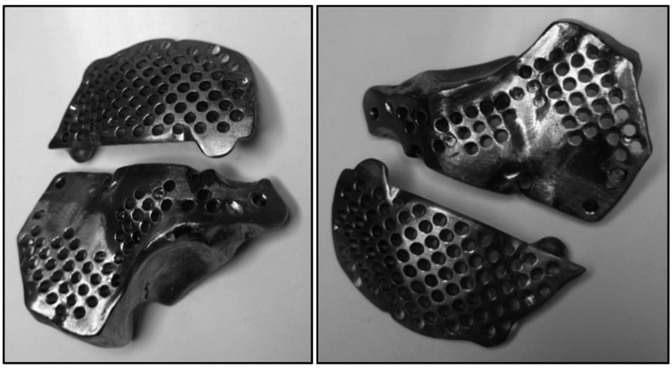

Fig. 16. The two pieces of the implant after finishing procedures.

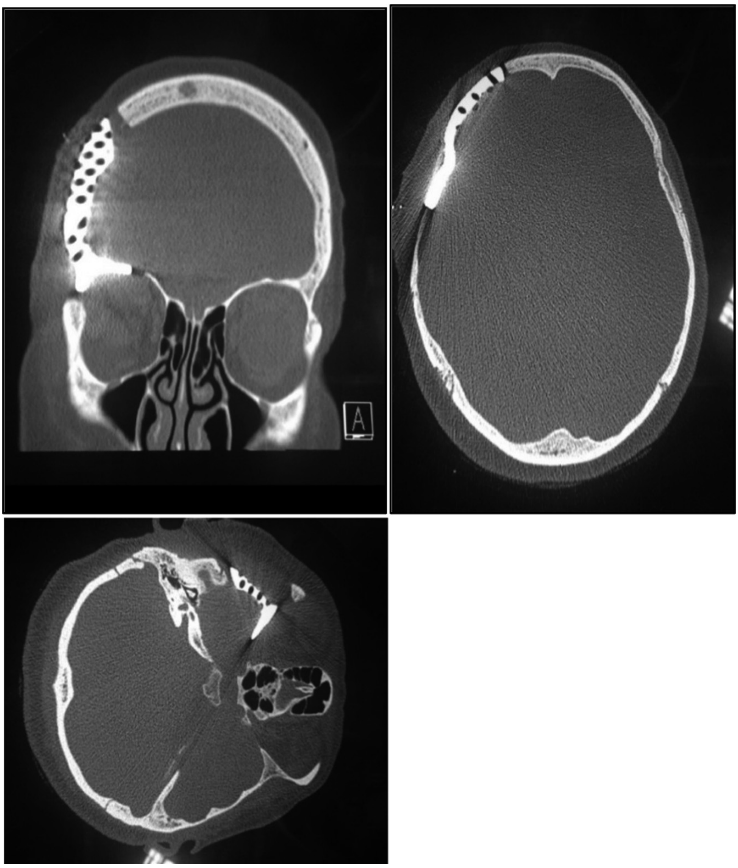

Fig. 17. CT scan of the patient several weeks after the operation.

6 Conclusion and Post-surgery

In conclusion the creation of a custom cranioplasty implant is a complex multistep procedure, requiring the collaborative work between doctors and engineers. It mixes the knowledge of additive and subtractive manufacturing technologies and material science with tomographic imaging and medical knowledge in terms of implants for the reconstruction of craniofacial injuries.

The results from the implanting procedure in real patient are shown on Fig. 17 and demonstrate how the advances in medicine and engineering allow the creation of biocompatible human spare parts with increased precision despite the complex shapes present in the human body. The images show the curve of the implant is following the curve of the skull. The patient showed very quick recovery and fast accommodation to the implant, due to the high level of achieved geometrical accuracy.

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